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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,738	12/06/1999	ERIC C. REYNOLDS	040268/0161	3015

7590 07/26/2002  
FOLEY & LARDNER  
3000 K STREET NW SUITE 500  
PO BOX 25696  
WASHINGTON, DC 200078696

EXAMINER

LUKTON, DAVID

ART UNIT PAPER NUMBER

1653

DATE MAILED: 07/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/380,738

Applicant(s)

Reynolds

Examiner

David Lukton

Art Unit

1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 8, 2002
- 2a) ☐ This action is FINAL.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-11, 15-26, and 41-61 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-7, 9-11, 15-26, and 41-61 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Pursuant to the directives of paper No. 20 (filed 5/8/02), claims 1, 3-7, 9-11, 15, 25, 42, 43, 45-47, 49 have been amended, claims 50-61 added, and claims 14, 30-38 cancelled. Claims 1-7, 9-11, 15-26, 41-61 are pending. Applicants' arguments are acknowledged herewith. A response will be forthcoming after applicants have elected an invention in according with the following.

\*

Restriction to one of the following inventions is required under 35 U.S.C. §121 (the numbering of groups begins with "IV" to avoid conflict with the previous restriction):

IV. Claims 1-7, 9-11, 15-26, 41-61, drawn to a complex (and methods of use thereof) which is not only formed under alkaline conditions, but is characterized as alkaline.

V. Claims 1-7, 9-11, 17-26, 41-61, drawn to a complex (and methods of use thereof) which may have been exposed to alkaline conditions at one point, but is not necessarily alkaline in the final isolated form.

With the exception of claims 15 and 16, all claims are common to both groups.

Group V encompasses the possibility of a complex which is formed by exposing the

complex to alkaline conditions at some point during the process, but is then acidified. By way of analogy, consider the case of hemoglobin, which has an isoelectric point (IEP) of about 7. Consider the following claims:

- 100. A salt of hemoglobin which is formed at pH 6.*
- 101. A composition comprising the salt of claim 100 in combination with a pH 8 buffer.*
- 102. A composition obtained by a process comprising*
  - (a) combining hemoglobin with a carrier to form a mixture, wherein said carrier contains water,*
  - (b) adjusting the pH of said mixture to 6.0;*
  - (c) optionally, lyophilizing the mixture of step (b) and*
  - (d) isolating the mixture of step (c).*

Claim 100 does recite that the salt is formed at pH 6, but as is evident from claim 101, this is not particularly meaningful as such, since upon placing the hemoglobin in pH 8 buffer, the effects of forming the salt at pH 6 are negated. By contrast, in the case of claim 102, the composition must contain acidified hemoglobin. Instant claim 1 is neither a "product by process claim", nor does it characterize the complex as alkaline. Accordingly, claim 1 encompasses both alkaline and acidic complexes. The situation is further complicated because, as is evident from claim 50, a pH of "about" 7 is, in applicants view, alkaline. The term "about 7" could easily encompass a pH of 6.7, which is not alkaline. Complicating

matters further are claims 54 and 55, which unequivocally and specifically permit a very acidic pH. These latter claims clearly encompass the possibility of the following process:

- (a) combining the phosphopeptide with inorganic phosphate at pH 9;*
- (b) combining with a carrier;*
- (c) reducing the pH to 5; and*
- (d) isolating the composition*

These latter claims would also encompass the following process:

- (a) combining the phosphopeptide with inorganic phosphate at pH 9,*
- (b) reducing the pH to 5;*
- (c) combining with a carrier, which is itself at pH 5; and*
- (d) isolating the composition.*

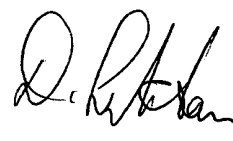
In the event that applicants elect Group IV, it is suggested that the characterization of the complex as being alkaline be reinstated. The possibility of a product-by-process claim would be considered in the case of claims drawn to a complex, but this would still leave the composition claims open to interpretation, since such claims would encompass the possibility of an acidic carrier being used.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID LUKTON  
PATENT EXAMINER  
GROUP 1800